Decision Memo for Partial Thromboplastin Time (PTT) (Addition of ICD-9-CM V58.83, Encounter for therapeutic drug monitoring, as a covered indication) (CAG-00338N)

Decision Summary

CMS has determined that ICD-9-CM diagnosis code V58.83, Encounter for therapeutic drug monitoring, flows from the existing narrative for conditions for which a PTT test is reasonable and necessary. We shall modify the list of "ICD-9-CM Codes Covered by Medicare Program" in the NCD for Partial Thromboplastin Time (PTT) by adding V58.83.

Back to Top

Decision Memo

This coding analysis does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue a change to the list of ICD-9-CM Codes Covered that are linked to one of the negotiated laboratory NCDs. This decision will be announced in an upcoming recurring update notification in accordance with CMS Pub 100-4, Chapter 16, Section 120.2 and will become effective as of the date listed in the transmittal that announces the revision.

TO: Administrative File: CAG – 00338N Addition of ICD-9-CM V58.83, Encounter for

therapeutic drug monitoring, as a covered indication for the Partial

Thromboplastin Time (PTT) National Coverage Determination

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SUBJECT: Addition of ICD-9-CM V58.83, Encounter for therapeutic drug monitoring, as a

covered indication for the Partial Thromboplastin Time (PTT) National Coverage

Determination

DATE: October 3, 2006

I. Decision

CMS has determined that ICD-9-CM diagnosis code V58.83, Encounter for therapeutic drug monitoring, flows from the existing narrative for conditions for which a PTT test is reasonable and necessary. We shall modify the list of "ICD-9-CM Codes Covered by Medicare Program" in the NCD for Partial Thromboplastin Time (PTT) by adding V58.83.

II. Background

On July 24, 2006, CMS formally accepted a request for consideration to add ICD-9-CM code V58.83 to the covered indication code list for the Partial Thromboplastin Time NCD.

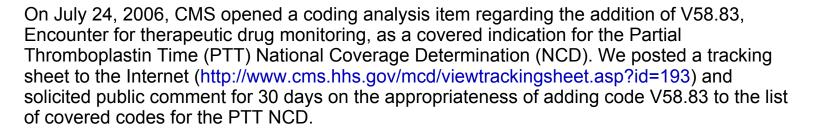
III. History of Medicare Coverage

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the laboratory NCDs, CMS determined that specific tests were reasonable and necessary for certain medical indications. These decisions were evidence-based, relying on scientific literature reviewed by the negotiating committee. The NCDs contain a narrative describing the indications for which the test is reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM Codes Covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM Codes Denied," and lists diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM Codes That Do Not Support Medical Necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary.

IV. Timeline of Recent Activities



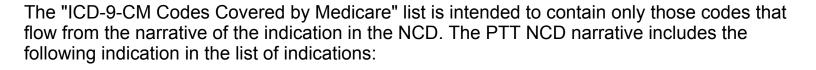
We did not receive any comments during the comment period, which ended August 23, 2006.

V. General Methodological Principles

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. Thus, all of the codes in the covered code list must flow from the narrative indications of the NCD. We reiterated this position in the November 23, 2001 final rule (66 FR 58795) and in subsequent implementing instructions (Program Memorandum AB-02-110).

On February 25, 2005, we announced in a final notice in the Federal Register (70 FR 9355) that we would maintain the accuracy of the coding lists without substantive changes to the narrative policy through an abbreviated process that did not require scientific evidence. We call this abbreviated process the Coding Analysis for Laboratories (CAL).

VI. CMS Analysis



"The PTT is most commonly used to quantitate the effect of therapeutic unfractionated heparin and to regulate its dosing."

ICD-9-CM instructs that when using code V58.83, "use additional code for any associated long-term (current) drug use." ICD-9-CM instructions further state that V58.83 excludes "blood-drug testing for medicolegal reasons."

We believe that ICD-9-CM code V58.83 flows from the narrative portion of the PTT NCD since a provision to quantitate, or measure, the effects of a therapeutic drug (heparin) is listed as an indication and is applicable to the definition of V58.83, Encounter for therapeutic drug monitoring. Therefore, we determined that V58.83 should be included on the list of "ICD-9-CM Codes Covered by Medicare Program" for the PTT NCD. Clearly, the coverage of PTT testing under this code is only reasonable and necessary when the therapeutic drug being monitored is heparin. We expect that contractors would deny claims for PTT testing under this code for any other drug.

We intend to issue a recurring update to the edit module implementing the NCDs to add ICD-9-CM code V58.85 to the list of the ICD-9-CM codes covered for the PTT NCD.

Back to Top

Bibliography

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Laboratory Test Handbook, 3 rd Edition. Jacobs D, Demott W, Finley P, Horvat R, Kasten B, Tilzer L eds. Lexi-Comp Inc., Ohio, 1994.
Back to Top